



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3106]

Animal Food; Export Certificates; Food and Drug Administration Food Safety Modernization Act of 2011; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fees we will assess for issuing export certificates for animal food. The FDA Food Safety Modernization Act (FSMA) of 2011 authorizes us to charge fees to cover our costs associated with issuing export certificates for regulated food including animal food. This notice provides the fee schedule for issuing these certificates and the basis for the fees. We have not previously collected fees to issue export certificates for animal food.

DATES: The fees described in this document for export certificates for animal food will be effective October 1, 2015.

FOR FURTHER INFORMATION CONTACT: Joanne Kla, Office of Surveillance and Compliance, Center for Veterinary Medicine (HFV-235), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5605, CVMExportCertification@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In April 1996, a law entitled the “FDA Export Reform and Enhancement Act of 1996” (Pub. L. 104-134, amended by Pub. L. 104-180) amended sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FD&C Act provides that persons exporting certain FDA regulated products may request FDA to certify that the products meet the requirements of section 801(e)(1), section 802, or other applicable requirements of the FD&C Act. Section 801(e)(4) of the FD&C Act also requires FDA to issue certification within 20 days of receipt of the request and authorizes us to charge up to \$175 for each certification issued within 20 days. In January 2011, section 801(e)(4)(A) of the FD&C Act was amended by FSMA (Pub. L. 111-353) to provide authorization for export certification fees for regulated food, including animal food (referred to as animal feed in section 107(b) of FSMA). Section 801(e)(4) of the FD&C Act authorizes FDA to issue export certificates for regulated food, drugs, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are legally exported under section 801(e) or 802 of the FD&C Act. The focus of this notice is on export certificates issued by the Center for Veterinary Medicine (CVM) for animal food.

II. Fees to be Assessed for Export Certificates

CVM estimates the costs of the export certification program for animal food to be approximately \$548,000 per year for payroll and operating expenses. There are four cost categories for preparing and issuing export certificates in general. They are: (1) Direct personnel for research, review, tracking, writing, and assembly; (2) purchase of equipment and supplies used for tracking, processing, printing, and packaging. Recovery of the cost of the equipment is calculated over its useful life; (3) billing and collection of fees; and (4) overhead

and administrative support. In fiscal year (FY) 2014 CVM issued approximately 933 animal food export certificates. Because CVM has not been charging fees for issuing export certificates for animal food, the program has been covered by appropriated funds.

As mentioned previously in this document, FDA may charge up to \$175 for each certificate. Certificates for some classes of products, including animal food, cost the Agency more than \$175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost FDA less than \$175 to prepare. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced FDA costs for preparing those certificates.

The following fees will be assessed starting October 1, 2015, for animal food export certificates:

Table 1.--CVM Fees for First, Second, and Subsequent Export Certificates

Type of certificate	Fee (dollars)
First certificate	\$175
Second certificate for the same product(s) issued in response to the same request	\$155
Subsequent certificates for the same product(s) issued in response to the same request	\$70

The fee for issuing the first export certificate for animal food will be at the maximum allowable amount and consistent with the export certification fees assessed since FY 1997 by other FDA Centers that provide export certification for drugs and devices. The fees for issuing subsequent certificates continue to differ among the Centers, based on varying costs.

Dated: September 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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